

September 10, 2018

Seema Verma Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 445-G Washington, D.C. 20201

SUBJECT: CMS-1691-P, Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS, Proposed Rule, Federal Register (Vol. 83, No, 139), July 19, 2018

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the proposed changes to the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) as outlined in the Centers for Medicare & Medicaid Services' (CMS) calendar year 2019 end-stage renal disease prospective payment system proposed rule.

CHA shares CMS' goals of transforming the health care delivery system — and, in particular, the Medicare program — by emphasizing patient-centered care and ensuring providers can direct their time and resources to addressing patient needs and improving outcomes. We applaud the agency's steps, in both the DMEPOS CBP March interim final rule and the July proposed rule, to acknowledge some of the ways in which the DMEPOS CBP's current design limits its ability to meet those shared goals.

California hospitals and post-acute care providers report significant difficulties in obtaining timely delivery of medically necessary durable medical equipment (DME) for Medicare beneficiaries upon hospital discharge. Since the implementation of the DMEPOS CBP, this issue has become increasingly acute. While similar challenges have been reported in both competitive bid and non-competitive bid areas across California, the frequency of delays is most problematic in CBP areas. A comprehensive approach is needed to address patients' and providers' concerns about obtaining DME.

CHA supports CMS' proposal to effectively delay the recompete process for DMEPOS CBP contracts and allow the current contracts to end December 31, 2018. This would allow beneficiaries — effective January 1, 2019 — to receive DMEPOS from any willing supplier until new contracts are awarded. This presents an opportunity for the agency to actively engage stakeholders to solicit additional ideas for program improvements, beyond the rate changes proposed, that will bring about changes that are needed. More specifically, we believe strongly that a number of changes should be made to the

DMEPOS Supplier Quality Standards, which apply to all suppliers — not just those that participate in the CBP. Further, we urge the agency to reconsider how this program is administered across the agency and look for additional opportunities to streamline oversight and increase transparency. Our more detailed comments and recommendations are noted below and in the attached issue brief.

Many Changes Are Necessary to Address Current Program Challenges

In anticipation of rulemaking, and in collaboration with CMS' Office of the CBP Acquisition Ombudsman as well as other interested stakeholders, we have worked with our member hospitals and post-acute care providers to document the challenges case managers experience daily in obtaining medically necessary DME for Medicare beneficiaries upon discharge. CHA has developed the attached issue brief, which summarizes months of data collection and provider experience, in an effort to demonstrate root cause issues that contribute to decreased access and delays in hospital discharge. **These issues cannot be addressed through payment reform alone.**

Changes to the CBP — beyond rate setting — are needed to ensure Medicare beneficiaries have access to medically necessary DME, and that DME is provided at the right time to ensure a safe discharge from the acute or post-acute care setting. Aligning performance-based metrics and creating incentives for suppliers to compete on customer service as well as price are the definition of value. Providers must no longer bear the administrative burden or costs. The goals of high-quality, affordable health care for our patients are shared goals. Therefore, we urge the agency reflect on the concerns articulated in the attached and strongly consider the following recommendations going forward.

Policy Recommendations

CHA urges CMS to consider the following short- and long-term policy recommendations to improve access to DME for Medicare beneficiaries.

- Convene stakeholders including providers, suppliers, contractors, the Competitive Bidding
 Liaison, the CBP Acquisition Ombudsman, DME Medicare administrative contractors and CMS
 policy staff, including leadership to discuss the root causes of program issues. A town hall,
 listening sessions and opportunities for dialogue between the agency and stakeholders would
 further inform future work, create shared understanding of the challenges and foster creative
 problem solving and common-sense solutions that could be considered through appropriate
 rulemaking and sub-regulatory guidance changes.
- Revise the DMEPOS supplier quality standards to further clarify the term "timely as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician." Revisions to the timely delivery quality standards should, in the case of a patient discharge from a hospital or other provider, require delivery of DME items that the ordering physician determines are essential for patient safety and continued recovery prior to the patient's discharge date, as specified by the providers and ordering physician.
- Remove the reference in the DMEPOS supplier quality standards to a five-day window for order response, specifically for DME items that are needed for safe discharge to home or community.
- Increase oversight and establish transparent performance metrics for assessing whether suppliers meet each quality standard. Incorporate these metrics and reporting into future CBP contracts
- Make transparent the process to ensure supplier compliance with the DMEPOS supplier quality standards and other program requirements, and take steps to improve agency oversight and supplier accountability.

- Make efforts to improve the DME supplier directory to assist beneficiaries and case managers in more efficiently identifying suppliers that are able to meet their needs. Improvements may include real-time equipment availability status, estimated delivery times and specific service delivery areas by DME supply.
- Reconsider the data CMS currently uses to assess CBP performance and supplier compliance.
 Recognize the limitations of the data including information not captured and identify alternative data collection mechanisms, such as provider and patient satisfaction surveys of all DME suppliers.

We remain committed to finding common sense solutions that promote program transparency, financial sustainability, improved access for beneficiaries and a reduction in the costly administrative and regulatory burden currently borne by providers in providing DME to beneficiaries.

In addition, CHA has considered the specific proposals outlined in the proposed rule and offers the following observations for consideration.

Product Category Recommendations

A common refrain by case managers across the state is frustration and added costs related to having to contact multiple suppliers for routine DME that patients often need at discharge to safely return home. These items include walkers and other standard mobility equipment, commodes and hospital beds. We agree with stakeholders that have expressed concerns about CMS' product pricing group categories, and we believe that discrete categories would promote fair and equitable payment rates. Grouping related DME products that are often requested together for safe discharge would limit the burden providers face when arranging delivery, set up and educational efforts among multiple suppliers.

Subdividing Larger CBAs

CMS seeks comments on whether certain core-based statistical areas (CBAs) should be split into smaller CBAs to "create a more manageable service area." CHA believes strongly that if the agency changes the DMEPOS supplier quality standards to ensure timely DME delivery, as requested, it may have no choice but to reconsider CBA size so that it can effectively oversee suppliers. Moreover, as noted in our issue brief, the size of the CBAs within each of these regions can be too large for the agency to detect access issues related to DMEPOS supplies. For example, within the broader "San Francisco-Oakland-Fremont, CA" CBA, beneficiaries could experience access problems in Fremont but not San Francisco. This issue is one that should be considered from both contracting and oversight perspectives.

Proposed Surety Bond Change

CHA supports CMS' proposal to require suppliers to forfeit their bid surety bond for a product category if their bid for the lead product is at or below the median of all bids in that category and they do not accept the contract.

Payments in Former CBAs During Gap Period

CMS' proposed policy to allow "any willing supplier" to provide bid items to beneficiaries in former CBAs will, we hope, open those markets up to a significantly larger number of suppliers. As a result, the volume of items any single DME supplier will be providing may decrease. We are hopeful that new entrants to the market will ease access issues. However, we are sympathetic to concerns that, in areas with only one reliable supplier, volume may decrease so significantly that the supplier would be unable

to sustain the financial losses and would leave the program. CHA urges CMS to develop and implement an oversight program that captures the quantitative and qualitative impacts of this policy, should it be finalized, and make the data available for additional analysis and consideration in future rulemaking.

CHA appreciates CMS staff's continued commitment to working with CHA in addressing these challenges and the opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688; or my colleague Pat Blaisdell, vice president continuum of care, at pblaisdell@calhospital.org or (916) 552-7553.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs

Enclosure: California Hospitals' Challenges in Obtaining Durable Medical Equipment for Medicare

Beneficiaries, September 2018.

California Hospitals' Challenges in Obtaining Durable Medical Equipment for Medicare Beneficiaries

September 2018

Introduction and Overview

California hospitals and post-acute care providers report significant difficulties in obtaining timely delivery of medically necessary durable medical equipment (DME) for Medicare beneficiaries upon hospital discharge. Since the implementation of the Centers for Medicare & Medicaid Services (CMS) Competitive Bidding Program (CBP) for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), this issue has become increasingly acute. While similar challenges have been reported in both competitive bid and non-competitive bid areas across California, the frequency of delays is most problematic in CBP areas. A comprehensive approach is needed to address patients' and providers' concerns about obtaining DME.

Failure to address DME access has had a growing and pervasive impact on the quality of patient care throughout California. In addition, the administrative burden and financial resources that hospitals and post-acute care providers must expend to register their complaints related to CBP DME suppliers — and, concurrently, to implement work-around strategies to obtain the medically necessary DME equipment for patients — have grown exponentially in recent years. CHA is committed to identifying workable solutions that will improve access to medically necessary DME for Medicare beneficiaries and to working with the agency in improving the CBP program.

Survey Background

In March of this year, CHA initiated several quantitative and qualitative data collection efforts to document hospital and post-acute care provider case managers' experiences in obtaining DME for patients, with the goal of identifying solutions that will improve beneficiary access to DME. In August 2018, CHA surveyed member case management staff on their overall perceptions and experience in obtaining DME for their Medicare beneficiaries across the state in both CBP and non-CBP areas. The survey instrument and summary results are available on request. From April to August 2018, CHA member case management staff were asked to report challenges in obtaining DME for beneficiaries in CBP areas. This included recording their communications with all suppliers listed in the supplier directory for the applicable CBP zip codes and reporting which suppliers were or were not able to provide equipment on a weekly basis. In addition, case managers reported to the Competitive Bidding Liaison (CBL) situations in which staff were unable to obtain the equipment as needed to ensure a timely and safe discharge from the acute or post-acute care setting. Despite contacting the CBL for assistance, it was often the case that DME was not available to beneficiaries at the time of a planned discharge, leaving many hospitals to provide equipment at their own expense or delay discharge.

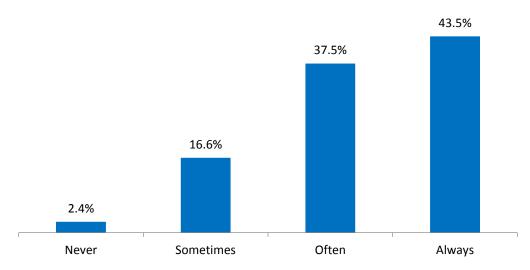
This data collection effort illustrates California's continuing beneficiary access challenges, which are not captured in the CMS data used to monitor the program and ensure supplier compliance. Key findings are summarized below.

The California DME Experience

CHA member hospitals and post-acute care providers continue to report a number of concerns about the performance of CBP DME suppliers that are contracted to provide DME equipment and appear in the Medicare supplier directory. Consistent and repeated complaints include:

- Lack of responsiveness to phone calls and electronic communication during business hours, as well as non-response during non-business hours
- Extended periods of DME equipment delivery delays or out-of-stock equipment
- Suppliers unable or unwilling to deliver DME to the hospital prior to discharge date;
 alternatively, suppliers agree to a date but do not follow through leaving case management to start the process again and further delaying patient discharge
- Drop-ship "delivery" to patients rarely accompanied by the required assembly, set up or training and education as required by the DME supplier quality standards
- Inappropriate requests of providers by suppliers for example, requiring specific language in medical documentation prior to order fulfillment, or repeated and inconsistent requests for additional and duplicative documentation that is not currently required
- Lack of an effective mechanism for providers to bring about a timely resolution, effectively
 delaying discharge or requiring a provider to purchase or provide DME equipment to the patient
 on a temporary basis
- No accessible alternatives or resources when services or equipment are not available for beneficiaries, necessitating a longer than anticipated hospital or post-acute care stay

Figure 1: Frequency of Issues Accessing Basic DME Items for Medicare Beneficiaries



Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

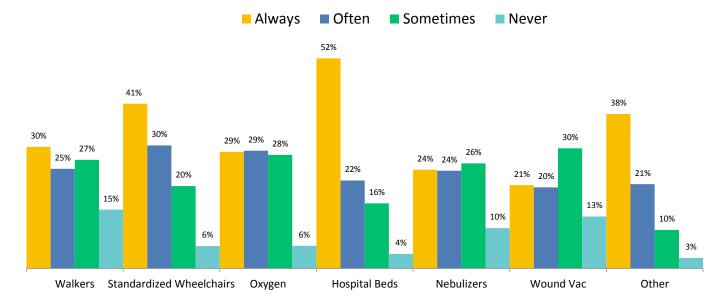


Figure 2: Frequency of Delays Obtaining DME, by Item Type

Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

Case managers' daily experiences reveal several system-wide issues related to timely access to DME equipment; these issues must be addressed comprehensively. In the interim, hospitals and post-acute care providers have managed to develop and implement costly "work-arounds" for supplying DME to Medicare beneficiaries to ensure safe discharge. For instance, many facilities report that they now routinely purchase a supply of frequently ordered items, such as front-wheeled walkers, and provide them to patients at the hospital's expense. Others keep a supply of donated items or give patients the option to purchase the item themselves to avoid a delay. Some hospitals have considered arranging with select suppliers to stock an on-site closet, with hospital personnel issuing the equipment. These methods are costly to patients and providers, and ultimately mask the program's problems.

Hospitals express confusion and concern about establishing these "work-arounds," including how they should be managed and how they relate to existing Medicare policy. Providers also state that they felt compelled to implement these extraordinary processes to ensure that Medicare beneficiaries receive timely care and are not subject to an unsafe discharge.

Providers' efforts to implement creative solutions for obtaining DME obscure the program's underlying and systematic issues, which remain unaddressed.

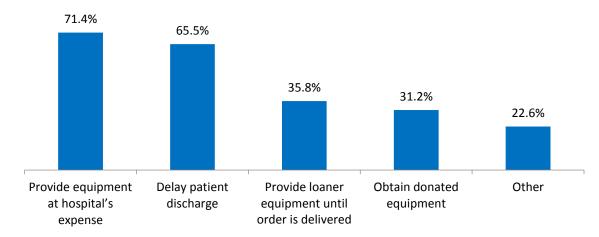


Figure 3: Hospital Methods of Facilitating Discharge when DME is Unavailable or Delayed

Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

Key Findings

DME Supplier Directory is Out of Date and Contributes to Provider Administrative Burden

To obtain DME for beneficiaries, hospital-based case managers and other clinical personnel access lists of designated suppliers on the online CMS supplier directory at www.medicare.gov/supplierdirectory/search.html. This directory, which is updated quarterly, provides information on contracted suppliers and what DME is included in the CBP for that region. Under the CBP, case managers who are unable to obtain the needed DME from the first supplier they contact must continue contacting listed suppliers until they are able to find one who can fulfill the order. Moreover, the inaccuracy of the supplier directory results in case managers making numerous calls to suppliers that are unresponsive and unable — or unwilling — to fulfill an order. This process is inefficient and administratively burdensome to providers.

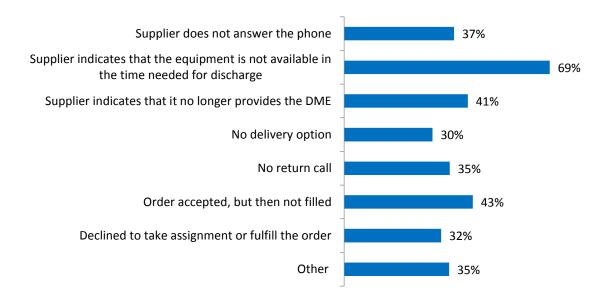


Figure 4: Issues Reported When Trying to Order DME

Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

Case managers routinely report their frustrations that suppliers listed in the DME supplier directory do not respond to their calls (35 percent) or decline to provide DME in their contracted area (30 percent). Sixty-nine percent of case managers note that the suppliers listed in the directory indicate there is no equipment available in time for the anticipated patient discharge, and another 41 percent of case managers report that, when contacted, the supplier indicated it no longer provides that DME. When a referral agent finally finds a supplier that answers the phone and agrees to accept an order, 43 percent of case managers note that the order is then not filled, and the process starts all over again. As a result, hospitals have a limited number of suppliers from which they can order, despite several options listed in the CMS supplier directory; in some instances, no other supplier is available.

CHA member hospitals were asked to make calls to designated suppliers in their respective CBP zip codes to obtain information on availability of frequently requested DME. Of the 226 reported calls made to suppliers over several weeks, on average, four out of 10 suppliers listed in the CMS supplier directory did not respond to orders for DME for their designated zip code(s), and thus were not actual options for hospital personnel seeking equipment for their patients.

CMS guidance and guidance from CBL instruct providers, or "referral agents," to contact **all** suppliers listed in the directory until finding one that has the needed equipment available; can deliver or dropship the DME to the hospital in time for patient discharge; and, when needed, can have a technician onsite to educate and train the beneficiary, as required by the DME quality standards. **The lack of updated data in the supplier directory requires, at a minimum, weekly — if not daily — calls to all contracted suppliers.** This inefficient process imposes both financial and personnel costs, borne exclusively by hospitals, and leads to delays in access to DME for beneficiaries.

Not having a steady and reliable resource for routinely ordered DME creates a significant and costly administrative burden for providers. Case management staff are diverted from other duties, like patient and caregiver education and training, or care coordination. Further, the lack of reliability adds costs and unnecessary administrative burden to the health care system.

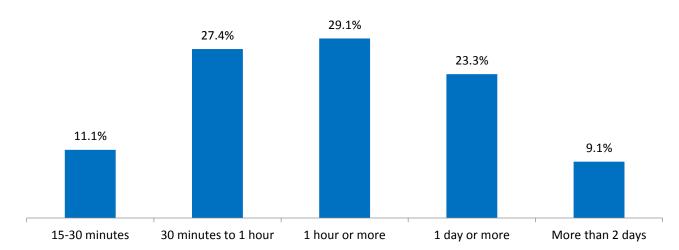


Figure 5: Average Time Spent to Obtain DME* (per Medicare beneficiary)

Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

*Note: This question implied that the order was accepted, but not necessarily delivered or filled.

In 2017, the hourly rate paid to a hospital case manager in an acute care setting in Northern California was \$80.60 (including benefits)¹. The time hospital case managers spend, per patient, to obtain DME for a Medicare beneficiary ranges from an hour or more (29 percent of case managers) to one to two days (23 percent). Nine percent of case managers report spending more than two days to identify DME suppliers that are able to assist. If a case manager had five patients to discharge per day and spent one hour to identify a DME supplier able to meet beneficiary's need, the process would cost the organization \$147,095 per year — a conservative estimate at best.

While the direct salary cost is significant, the time spent fruitlessly seeking DME diverts case management staff from other critical patient care and care coordination activities that would improve patient outcomes and patient experience of care. For example, an hour spent on the phone trying to find a walker is an hour that the clinician could have spent training the patient on using the walker at home or navigating stairs.

Case Examples

A hospital in Central California reported that, in the process of ordering a front-wheel walker, it contacted each of the 17 suppliers listed on the CMS supplier directory for its area. Of these, six did not answer a phone call or respond to a message, and three reported that they did not serve the designated

¹ Hospital Association of Southern California 2017 Salary Survey

beneficiary zip code. The remaining eight listed suppliers indicated an interest and willingness to respond to orders. The CBL agreed to investigate specific instances in which suppliers did not respond to initial calls, and later confirmed that the suppliers had been contacted and educated. Without timely removal of non-responding suppliers, this hospital has to repeat the same exercise on a weekly or biweekly basis to obtain DME for beneficiaries.

CHA believes a more robust DME supplier directory would be a good first step in improving efficiency for referral agents. In addition, we believe it could evolve into an important oversight tool for CMS. CHA suggests the following supplier directory improvements:

- The supplier directory should be updated on a more timely basis and, eventually, in real time.
 Quarterly updates are not sufficient.
- CMS should take steps to incorporate data about equipment availability status, estimated
 delivery timelines, more specific information related to on-site delivery service areas and
 estimated delivery times. With enhanced technology, this data could be updated in real-time
 and could be a more robust oversight mechanism for monitoring access.
- CMS should indicate in the directory if a supplier is temporarily unable to fill orders. Further, if CMS removes a supplier from the directory, it should be reflected immediately — not after the next quarterly update.

DME Supplier Quality Standards Do Not Meet Medicare Beneficiaries' Needs

The DMEPOS quality standards² lay out specific requirements for all suppliers that accept Medicare assignment. Hospitals continue to report experiences with suppliers that appear to violate these standards — in particular, the requirement that suppliers "deliver and set up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician."

More specifically, the quality standards require that suppliers hire technical personnel who are competent not only to deliver and set up equipment, but also to train beneficiaries and caregivers. Delivery of DME items is specifically covered by CFR 424.57(c)(12), which states:

The supplier: (12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively.)

These standards go on to note that suppliers must "provide the equipment in the time scheduled. The delivery person must be knowledgeable about the equipment." Further articulation of these requirements is described in Section C. Training/Instructions for the Beneficiary and Any Caregivers:

²www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf

Suppliers must "ensure that the beneficiary and any caregivers can use all equipment and item(s) provided safety and effectively in the settings of anticipated use."

Lastly, the customer service standard that allows suppliers five calendar days to notify a prescribing physician or referral agent that the "supplier cannot or will not provide the equipment" is increasingly problematic.

Effective and safe hospital discharge depends upon the availability of medically necessary equipment and supplies in a timely fashion. Clinicians prescribe DME to address the individual beneficiary's specific clinical or functional needs. For example, basic mobility equipment (e.g., a front-wheeled walker) is necessary for a patient to safely move to and within the home setting; sending an individual home without this equipment compromises his or her safety, independence and outcome.

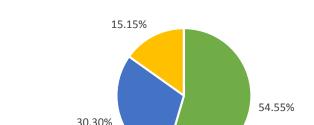
In 2017, the average length of stay for an inpatient admission ranged from 4.6 days in our nation's smallest hospitals (fewer than 25 beds) to as high as 5.5 days in large, academic medical and urban centers (more than 500 beds). This is a short window, and a patient's specific DME needs may not be known until shortly before discharge. Typically, a case manager has only 24 to 48 hours' notice of DME items that will be needed; sometimes, that period is even shorter. Prior to discharge, staff seek to obtain DME so that they are able to properly set up the equipment and fit and train beneficiaries on their specific equipment, thereby preventing quality of care issues. The ability to access routine items with a quick turnaround is critical to ensuring timely and safe discharge.

The preferred standard of care, historically, has been to ensure delivery to the patient at the time of hospital discharge so that clinical staff can provide the necessary individualized assessment and training. As noted in Figure 2, above, case managers report delays in obtaining routine DME; contacting multiple suppliers in an unreliable supplier directory does not result in a faster delivery. The quality standard that allows suppliers up to five calendar days to notify the prescribing physician and referral agents that they cannot — or will not — provide DME is unacceptable, and significantly contributes to delays in hospital discharge as well as limited beneficiary access.

Drop-ship delivery and remote instructions, in most cases, do not adequately "ensure that the beneficiary and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use." Effective use of DME requires that patients receive individualized fitting, assessment and training that cannot be provided remotely or through video instruction. Fit, use and safety concerns will differ widely based on individual patient characteristics and care setting. Even something as "simple" as a walker must be fit appropriately for the patient and, depending on the nature of the mobility impairment and the individual's unique needs, its use will vary.

This causes case managers great frustration. Suppliers that do respond to the referral agent quickly often report that they require several days or weeks to comply with an order. If the average length of stay for hospital inpatients is five days, it is unrealistic to expect patients to wait — at a minimum — another five days for timely DME delivery.

Hospitals were asked to report to the CBL challenges in receiving requested assistance. The CBL has advised referral agents that the current policy, as described above, allows suppliers up to five days for a response. Hospitals and post-acute care providers are beyond frustrated with this response. Because this has been the CBL's consistent response over time, less than 9 percent of case managers reported during our period of data collection³. Case managers who sought CBL assistance were rarely satisfied, as evidenced by the chart below. In fact, 72 percent of case managers noted that they would not contact CBL for assistance.



■ Very Poor
■ Poor
■ Average

Figure 6: Case Managers' Performance Rating of CBL Assistance in Obtaining DME

Source: CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018

Case Examples

In the case of the hospital described above, the case manager was able to confirm eight active suppliers for a front-wheel walker. Delivery time frames ranged from two business days to six weeks. Only one supplier indicated that it would be able to deliver directly to the hospital. In practice, however, the hospital case manager found that needed equipment from this supplier was frequently out of stock, delaying delivery from four days to two weeks. When the hospital reported this and other delivery issues, the CBL representative again noted that current quality standard guidelines allow suppliers up to five days to respond to an order — that is, the supplier has five days to let the hospital or clinician know whether it will be able to fulfill the order. The CBL has communicated on many occasions that there is no specific timeline for delivery.

Other hospitals reported similar experiences. Of 187 reported supplier contacts, only 44 — fewer than 25 percent — indicated typical delivery times of three days or fewer. Even in these cases, most suppliers provided a range (e.g., three to five days). Others reported that they delivered to specified areas only one day a week or only on certain days; in at least one case, the supplier indicated that it did not deliver at all, instead requiring the beneficiary to come to its storefront for pickup.

³ CHA Survey of Hospital and Post-Acute Care Case Managers, August 2018. Survey response rate: 416 California case managers.

Other delivery problems include wide use of drop-ship and curbside delivery, as well as lack of adequate beneficiary instruction and education. Hospitals reported that many suppliers would deliver on a drop-ship basis only, requiring that the patient or caregiver assemble. While most suppliers that were asked said they provided "some" patient education and instruction, at least 16 indicated they do not provide any. Several others indicated that they would be able to answer questions by phone or would provide instruction if the beneficiary traveled to their retail locations. The lack of access to direct delivery and specific education and instruction compromises beneficiaries' ability to use the equipment safely and effectively, and undermines their ability to achieve desired outcomes.

In another case, a hospital reported that, of 10 designated suppliers, only one agreed to provide a hospital bed, through a subcontract arrangement with another contractor. The bed was delivered with a broken guardrail. Follow-up required several phone calls, in part because the supplier and subcontractor each held the other entity responsible. The subcontractor ultimately offered to ship a new bed rail. Due to safety concerns, the beneficiary's family requested that a service technician assist with installation. However, the supplier stated that it was unable to send out a service technician because it is located out of state, and further stated that DME companies are not required to do so. Moreover, the supplier noted that it would not be liable if the beneficiary's family assembled the item.

While CMS has recently, through rulemaking, proposed significant revisions to the CBP that will affect DME payment rates, fundamental underlying challenges related to DME suppliers' performance remain. Consistent interpretation, strict enforcement and further clarification of the DME supplier quality standards should be a priority.

Documentation Requirements Impede Access

Increased CMS oversight and important efforts to improve Medicare program integrity have created several unintended consequences that limit patient access to DME. CHA member hospitals report that suppliers communicate variable documentation requirements, including requests that are inconsistent with DME Medicare administrative contractor (MAC) guidance.

Case managers report that some suppliers begin processing an order only after all documentation requirements are completed and in hand. This limits the hospital's ability to plan ahead and provide lead time for an anticipated order. For example, the "face-to-face" visit may not occur until shortly before discharge; waiting to process an order until this visit is documented often results in a delay in hospital discharge.

While we agree that items should not be delivered until medical necessity and documentation requirements are met, case managers need to, at a minimum, confirm availability of a given item from a given supplier. Once confirmed, the case manager can proceed with working with the beneficiary and the supplier to ensure smooth and timely delivery of DME.

Case Example

A hospital reported that a supplier requested specific wording on orders; when the order did not meet those requirements, it would request revisions in the record. This request is inconsistent with guidance provided by the DME MAC, which states standardized language or language that repeats verbatim the local coverage determination (LCD) is unacceptable, and that Medicare does not require specific language to be included. The back-and-forth between referral agent and supplier to get the "right" wording increases delivery delays. When the hospital reported this concern to the CBL, the CBL representative indicated that documentation issues are not a CBL issue and referred it to Noridian, the DME MAC.

Suppliers often require that their own forms be completed, which — though not expressly prohibited — adds additional complexity to the ordering process. Hospital case manager seeking a particular item may need to contact multiple suppliers, each requiring different documentation and forms, before the order is accepted. Similarly, if a supplier is unable to fill an order after previously agreeing to, hospital personnel may need to recreate the entire order to move on to a different supplier.

The situation is further complicated when a designated supplier subcontracts with another supplier, either routinely or in response to a specific order. In these cases, hospital personnel may have to submit duplicate communication — once to the designated supplier and once to the subcontractor — and respond to multiple or conflicting requests.

Conflicting and inconsistent documentation requirements waste valuable resources and exacerbate delays in obtaining medically necessary services and items. CHA urges CMS and the DME MAC to consider the following efforts to improve communications and reduce administrative burden:

- Continue to conduct joint education, including suppliers and providers, to promote shared understanding of the required documentation.
- Where feasible, standardize documentation requirements and limit individual suppliers' modifications, which create administrative burdens and delay access.
- Make clear and enforce the communication and accountability requirements for subcontracting arrangements.

CMS Data Used to Monitor Beneficiary Access and Outcomes Are Inadequate

To monitor Medicare beneficiary access and health outcomes resulting from the Medicare DMEPOS CBP, CMS relies primarily on an approach that monitors three groups of beneficiaries in each of the four DME MAC regions and the national mail order competitive bidding area (CBAs)⁴:

- Enrolled Population all people in the CBA enrolled in Original Medicare
- Utilizers Original Medicare beneficiaries in the CBA who have a claim for one of the competitively bid products

⁴ www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html

 Access Groups – Original Medicare beneficiaries who are likely to use one of the competitively bid products for related health conditions. In the case of mail-order diabetes supplies, for example, CMS notes that the relevant access group would be composed of beneficiaries with diabetes.

CMS states that, within these groups, it monitors claims rates and a range of health outcomes, including deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled-nursing facilities, average number of days spent hospitalized in a month and average number of days in a skilled-nursing facility in a month. CMS concludes, based on analysis of its claims data, that no negative changes in beneficiary health outcomes in any group can be attributed to the CBP. While we commend CMS' efforts to monitor beneficiary access and health outcomes related to the CBP, we believe these data are inadequate for two primary reasons.

First, CMS examines these issues at the DME MAC region level, which spans large geographic areas and multiple states. For example, the West DME MAC region spans 17 states, including California, Kansas, Hawaii and Alaska. Any access problems in a given competitive bidding area would be masked or diluted by other changes occurring in the broader DME MAC region. These large geographic areas are too heterogeneous to detect access problems or other negative beneficiary outcome issues. Moreover, even the size of the CBAs within each of these regions can be too large to detect access issues related to DMEPOS supplies. For example, within the broader "San Francisco-Oakland-Fremont, CA" CBA, beneficiaries could experience access problems in Fremont but not San Francisco.

Second, these aggregate data mask important access issues to DMEPOS that may not ultimately result in negative outcomes — but only because hospitals or other stakeholders act to ensure that beneficiaries receive their DMEPOS and related supplies in a timely manner, despite suppliers' failure. As previously discussed, a hospital may provide a beneficiary a necessary item, like a wheelchair, at the hospital's own expense. In other cases, the hospital may delay discharging the patient until the DMEPOS supplier can provide the equipment. Both situations not only inconvenience the beneficiary, but also result in additional expenses to the hospital and the Medicare program. Because the hospital took action, no negative health outcomes would be reflected in the claims data, but this situation should be categorized as an access-related issue. The approach CMS currently uses to monitor access solely through review of claims data would not capture these, or similar, situations.

Overall, the comparison CMS makes over time for CBAs and non-CBAs is not useful in detecting important differences in DMEPOS access issues for beneficiaries at the local hospital market level. A more refined and granular approach is needed to detect meaningful differences that CMS can act upon as part of an ongoing monitoring approach. We believe that a quantitative approach — complemented by a qualitative approach, such as ongoing surveys or selective case studies of sites where issues have been reported — would improve CMS' efforts to monitor beneficiary access and health outcomes under the DMEPOS CBP and provide more actionable data to resolve access-related issues associated with the CBP.

Policy Recommendations

To address the access challenges, CHA urges CMS to consider the following short- and long-term policy recommendations to improve access to DME supplies for Medicare beneficiaries.

- Convene stakeholders including providers, suppliers, contractors, the CBL, the CBP
 Acquisition Ombudsman, DME MAC and CMS policy staff, including leadership to discuss the
 root causes of program issues. A town hall, listening sessions and opportunities for dialogue
 between the agency and stakeholders would further inform future work, create shared
 understanding of the challenges and foster creative problem solving and common-sense
 solutions that could be considered through appropriate rulemaking and sub-regulatory guidance
 changes.
- Make efforts to improve the DME supplier directory to assist beneficiaries and case managers in more efficiently identifying suppliers that are able to meet their needs. Improvements may include real-time equipment availability status, estimated delivery times and specific service delivery areas by DME supply.
- Make transparent the process to ensure supplier compliance with the DME quality standards and other program requirements, and improve oversight and accountability.
- Revise the DME quality standards to further clarify the term "timely as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician." Revisions to the timely delivery quality standards should, in the case of a patient discharge from a hospital or other provider, require delivery of DME items that the ordering physician determines are essential for patient safety and continued recovery prior to the patient's discharge date, as specified by the providers and ordering physician.
- Remove the reference to a five-day window for order response, specifically for DME items that are needed for safe discharge to home or community.
- Increase oversight and establish transparent performance metrics for assessing whether suppliers meet each quality standard. Incorporate these metrics and reporting into future CBP contracts.
- Reconsider the data CMS currently uses to assess CBP performance and supplier compliance.
 Recognize the limitations of the data including information not captured and identify alternative data collection mechanisms, such as provider and patient satisfaction surveys of all DME suppliers.

To date, the CBP is the only Medicare program that lacks any measure of quality or value. Prior to CBP implementation, suppliers had to compete on customer service; suppliers with exceptional customer service were rewarded with business from case managers and beneficiaries. As Medicare continues in its current transition from fee-for-service to a more value-driven payment system, the CBP should also evolve. It is imperative that the agency, in consultation with stakeholders, develop metrics and performance-based standards that recognize DME suppliers that meet beneficiaries' needs. These metrics may include timely fulfillment of DME orders and delivery, accessibility of customer service representatives, and adherence to DME supplier quality standards. Section E of the current quality standards outlines a number of performance management metrics. However, these metrics — and

others — should be made transparent so that both providers and beneficiaries have access to information that would assist them in efficiently choosing appropriate DME suppliers. Requiring standardized, publicly reported metrics for all suppliers would also foster competition and improve DME supplier performance, and could be used to develop value-based payment strategies in the near future. Notably, any additional requirements in the short- or long-term would take time to both develop and implement as part of the CBP contracting process. Once implemented, supplier bids could fully reflect the level of customer service needed, and contracts could be awarded based on performance — subsequently reducing the administrative burden on providers.

Conclusion

Changes to the CBP that go beyond rate setting are needed to ensure Medicare beneficiaries have access to medically necessary DME and that DME is provided at the right time to ensure a safe discharge from the acute or post-acute care setting. Aligning performance-based metrics and pushing suppliers to compete on customer service as well as price are the definition of value. Providers must no longer continue to bear the administrative burden or costs. Our goals of high-quality, affordable health care for our patients are shared goals. Changes to this program will ensure access for DME beneficiaries.